January 15, 2025

Synovis Micro Companies Alliance
Julie Carlston
Senior Manager, Regulatory Affairs
439 Industrial Lane
Birmingham, Alabama 35211

Re: K242541
Trade/Device Name: Gem Zipclip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: December 18, 2024
Received: December 18, 2024

Dear Julie Carlston:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2025.01.15 22:11:19 -05'00'

Tek N. Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242541

Device Name

GEM ZIPCLIP

Indications for Use *(Describe)*

ZIPCLIP is indicated for use in surgical procedures to occlude blood vessels.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K242541

510(k) Summary

Prepared on: 2025-01-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Synovis Micro Companies Alliance
Applicant Address	439 Industrial Lane Birmingham AL 35211 United States
Applicant Contact Telephone	(224) 948-3775
Applicant Contact	Mr. Daniel Davis
Applicant Contact Email	daniel_davis@baxter.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	GEM ZIPCLIP
Common Name	Implantable clip
Classification Name	Clip, Implantable
Regulation Number	878.4300
Product Code(s)	FZP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K981645	Vitalitec Titanium Hemostatic Clip	FZP

Device Description Summary

21 CFR 807.92(a)(4)

The GEM ZIPCLIP (ZIPCLIP) is a sterile, single-use automatic microclip applier. Each device contains 15 titanium microclips. When applied on a vessel, microclips remain with the patient as permanent implants. ZIPCLIP is sterilized using irradiation. ZIPCLIP is for prescription use only and the use environment is the operating room.

The ZIPCLIP device is a pre-loaded, disposable, single-patient use mechanical assembly comprised of plastic and metal components. The applier device has (2) scissor-like handles that, when driven medially, close the distal jaws forming a closed clip that was preloaded in the device in the open configuration. When released, the handles return to their resting state and the closed clip disengages from the applier. Simultaneously, a new clip is automatically loaded into the distal jaws for consecutive firing. When ZIPCLIP is empty a lockout clip (anodized gold in color) deploys between the jaws, preventing them from closing.

The ZIPCLIP is a mechanical assembly comprised of plastic and metal components. The clips are composed exclusively of titanium (Grade 1) and are supplied sterile in a preloaded channel that is incorporated into the applier. The number of clips per applier is fifteen (15). The clips are stacked and contained in a magazine internal to the device. Clips cannot be reloaded once the stack is deployed and the applier is disposed of once emptied. Note, the ZIPCLIP preloaded microclips are the only clips that can be used with the ZIPCLIP device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

ZIPCLIP is indicated for use in surgical procedures to occlude blood vessels.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The ZIPCLIP is intended for blood vessel ligation. The Titanium Hemostatic Clip is intended for ligation of blood vessels. Although there are differences between the indication for use statements of the predicate and subject devices, the intended use (blood vessel ligation) is the same. Both devices are intended for ligation/occlusion of blood vessels. The additional indication for use language of the predicate Titanium Hemostatic Clip is not necessary for inclusion in the ZIPCLIP indications for use as it goes beyond the general purpose of the device to include design aspects and specific use recommendations that are more appropriate to be covered in the instructions for use. Additionally, the subject ZIPCLIP indication for use wording is very similar to the reference device and other clips and automatic/pre-loaded clip appliers on the market. No new or different concerns are raised in terms of safety and effectiveness of the subject device.

Technological Comparison 21 CFR 807.92(a)(6)

Many characteristics of the predicate device and the subject device characteristics are the same. The predicate and the subject device include the same basic microclip made out of identical base titanium material. The predicate and subject device clips are closed on a vessel using the same principle of operation via the use of a clip applier with the clip within the jaws and handles squeezed forming a closed clip.

Technological differences between the subject and predicate device were taken into consideration when determining substantial equivalence. The primary technological difference between the subject ZIPCLIP device and predicate Titanium Hemostatic Clip is that the ZIPCLIP device incorporates the microclip and clip applier together in one device and the predicate Titanium Hemostatic Clip requires the use of the separate clip applier. This difference does not introduce new questions of safety or efficacy as the final result of both devices is the same, a titanium microclip closed around the vessel. Performance testing shows that the ZIPCLIP microclip can be safely and effectively closed around vessels. Additionally, there are many devices on the market that combine clips and clip appliers into one device, such as the reference Covidien Premium SurgiClip III (K142869).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Baxter conducted bench testing a) to ensure safety and efficacy of the device, and that it performs for its intended use: blood vessel ligation; and b) to demonstrate there are no new questions of safety or effectiveness compared to the predicate device.

Bench performance testing to verify that ZIPCLIP reliably deploys the clips and ligates vessels was performed. ZIPCLIP deployment of microclips on simulated vessels and microclip ligation of simulated vessels was performed using benchtop models to verify the ZIPCLIP's ability to safely and effectively occlude blood vessels. Additional testing was performed to verify the ZIPCLIP microclip is appropriate for MR-Conditional labeling and validate that ZIPCLIP is safe and effective for the intended user population.

Clinical Testing Not Applicable

Conclusion: The GEM ZIPCLIP is substantially equivalent to the predicate device Vitalitec Titanium Hemostatic Clip. The design/ technological differences were found to not affect safety and effectiveness and are supported by design verification and validation activities performed. The non-clinical testing performed supports the safety of the subject device for its intended use.